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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/618,934

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Laurens Nicolaas Sierkstra

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NOVOZYMES NORTH AMERICA, INC.

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SUITE 1600

NEW YORK, NY 10110

EXAMINER

MOORE, WILLIAM W

ART UNIT

PAPER NUMBER

1656

DATE MAILED: 06/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/618,934

Applicant(s)

SIERKSTRA ET AL.

Examiner

William W. Moore

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 3 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 88-117 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 88-117 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

*Response to Amendment*

Applicant's Amendment filed 3 March 2006 has been entered, canceling claims 34-87 and introducing the new claims 88-117. The new claims are free of the rejection of record of claims herein under the second paragraph of 35 U.S.C. § 112 because claims 88, 96, 102, 106, 110 and 114, from which the remaining claims depend, each state a sequence identifier with which the recited positions for modification can be identified by correspondence to the amino acid positions of the mature subtilisin BPN' protease set forth in SEQ ID NO:7. The new claims are also free of (1) the objection of record of claims herein for failing to state a proper Markush group, (2) the obviousness-type double patenting rejection of record over the claims of US Patent No. 5,482,849 is withdrawn in view of changes in substituents recited for substitutions at positions 167 and 171, and (3) the provisional obviousness-type double patenting rejection over the claims of copending application serial No. 10/786,850. Moreover, the new claims are free of the prior art rejections of record based on the disclosures of Branner et al., WO 91/00345, Branner et al., WO 92/11357, Casteleijn et al., EP 0405901, Branner et al., US 5,482,849, and Aaslyng et al., US 5,665,587 and US 6,197,567.

Specific disclosures in the specification support the new recitations of isoleucine (I, Ile) and leucine (L, Leu) as substituents at positions corresponding to positions 167 and 171 of subtilisin BPN', as well as isoleucine at a position corresponding to position 194 in subtilisin BPN', in the new claims 88, 89, 91, 92, 96, 98, and 102. It is noted that the recitation of tryptophan as a substituent at positions corresponding to position 194 in subtilisin BPN' in the new claims 88 and 92 is supported by a disclosure in Table II at page 10 of the specification and a generic disclosure in the paragraph spanning pages 10-11 of the specification.

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The Amendment to the specification providing the new Sequence listing that sets forth the integral, 275-amino acid, sequence of the mature subtilisin BPN' in SEQ ID NO:7 as well as the partial amino acid sequences of thirty-four additional microbial subtilases indicating regions corresponding to the regions of the subtilisin BPN' amino acid sequence between positions 127 and 145, positions 156 and 172, and between positions 189 through 201 depicted in Figure 1 is also acknowledged, but is insufficient to overcome the objection of record to the specification for the following reasons.

*Objection to the Specification: Sequence Rules Compliance*

The specification remains objected to for reasons of record for lack of compliance with 37 CFR 1.821. It is agreed that the Drawing Description of Figure 1 at page 17 of the specification is an appropriate location for associating a sequence identifier with a sequence in Figure 1 and that the Drawing Figure itself need not be amended in order to comply with the Sequence Rules. It is also agreed that the amendment to the specification and revised Sequence Listing in both printed and computer-readable form are bona fide attempts to comply with the requirements of 37 CFR 1.821. These do not overcome the objection of record to the specification stated in the communication mailed 25 August 2005 because no Statement of Sameness, as required by 37 CFR 1.821(e), was present in the Response of 3 March 2006, because the description of Figure 1 at page 17 of the specification does not indicate that two gaps SEQ ID NO:7, the first between positions 146 through 155 and the second between positions 173 through 188, are absent from alignments of regions of the amino acid sequences of the other subtilases in Figure 1, and because none of the acronyms at the N-proximal ends of the sequences aligned in Figure 1, see the bottom of each of Figure 1's sequences, are provided together with the corresponding sequence identifier in the description of Figure 1 in the specification, e.g., SEQ ID NO:7 (BASPN), SEQ ID NO:8 (BSS168),

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where Table I of the specification does not supply all acronyms in the order in which they are stated in Figure 1. Compliance is required in response to this communication.

### *Claim Objections*

Claims 96 and 102 are objected to because of the following informalities: Clauses (b) of both claims erroneously recite the terms "Y167I, Y167L" where Applicant had intended to instead state "Y171I, Y171L". See, e.g., claim 98, where Y171I and Y171L appear. Appropriate correction is required to address this objection to claims 96 and 102, the following objection to claim 98 and to avoid several rejections stated below.

Claim 98 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim where it recites substitutions outside the scope of substitutions permitted in claim 96. Applicant is required to cancel the claim, or amend the claim to place the claim in proper dependent form, or rewrite the claim in independent form. In this case, amending claim 96 to state the substitutions Applicant actually intended will overcome this objection to claim 98.

Claim 96, 102 and 106 are separately objected to because of the following informalities: Clauses (b) of claims 96 and 102 do not agree with the preambles of the claims where their clauses (b) do not separately state "**a substitution** at position 171". and instead states multiple, exclusive, substitutions. Claim 106 similarly fails to recite **a substitution**". Appropriate correction is required.

### *Non-Provisional Double Patenting*

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting

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ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

A. Applicant indicates in the Response filed 3 March 2006 that a terminal disclaimer will be provided to overcome obviousness-type double patenting rejections of record based three patents issuing on applications that are parents of the instant application:

1. Claims 88, 90, 91, 93-96, and 99-109 remain rejected for reasons of record under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-28, 30, and 31 of U.S. Patent No. 5,837,517. While Applicant indicates that a terminal disclaimer will be filed upon an indication of allowable subject matter, the rejection must be maintained unless and until a terminal disclaimer is filed because the conflicting claims are not patentably distinct from each other.

2. Claims 88-117 remain rejected for reasons of record under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 6,190,900, particularly claim 1 of the patent. While Applicant indicates that a terminal disclaimer will be filed upon an indication of allowable subject matter, the rejection must be maintained unless and until a terminal disclaimer is filed where the conflicting claims are not patentably distinct from each other.

3. Claims 88-90 and 93-95 remain rejected for reasons of record under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 8, 10, 15, 21, 23, and 29-33 of U.S. Patent No. 6,682,924. Although Applicant indicates that a terminal disclaimer will be filed upon an indication of allowable subject matter, the rejection must be maintained unless and until a terminal disclaimer is filed.

B. Applicant's arguments in the Response filed 3 March 2006 cite *In re Berg*, 46 USPQ2d 1226 (Fed. Cir. 1998), in addressing the remaining obviousness-type double patenting rejections of record have been fully considered but they are not persuasive.



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Applicant suggests at page 10 of the Response that “a one way analysis of obviousness is the proper test when a later filed improvement patent issues before an earlier filed basic patent”. The appellate panel in *Berg* explained however that, absent special circumstances, the appropriate “one-way test” for obviousness-type double patenting is “whether the application claims are obvious over the patent claims” without regard to the order in which the application under examination and the application that issued as the patent were filed. 46 USPQ2d at 1229. Even though the patented claims relied on in the rejections of record were issued on later-filed applications, one of ordinary skill in the art reading the patented claims would consider them to render obvious the amino acid substitutions of the modified subtilases of the pending claims.

The court found that a “two-way test” should be applied in the special circumstance where claims of an earlier-filed, “basic”, application are rejected in view of patented claims of a later-filed, “improvement” application that render claims of the earlier-filed application obvious under the “one-way” test: This occurs when the USPTO decides to issue the later-filed application first as a patent and the two-way test requires that (1) claims of the pending application be obvious in view of the patented claims and (2) the patented claims are also obvious in view of the pending application claims. *Berg* at 1229. The court noted that two factors invoke the “two-way test”: (1) the administrative action of the USPTO that dictates issue of the later-filed application as a patent before the earlier-filed application despite Applicant’s diligence in prosecuting the earlier-filed application or, in the particular situation of *Berg* a simultaneously-filed “improvement” application, i.e., the later-filed application is not a continuation of the earlier, and (2) whether the applicant would have necessarily had to present the different claims in a different application, i.e., a common disclosure did not support both the patented claims and the pending claims under examination. 46 USPQ2d at 1230-31. Thus the following

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rejections of record are provided in the numerical order of the patents the claims of which were bases for rejections in the communication mailed 25 August 2005:

1. Claims 88, 89 and 95 are rejected for reasons of record under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, and 4 of U.S. Patent No. 5,631,217. Although the conflicting claims are not identical, they are not patentably distinct from each other where modified subtilases and detergent compositions comprising same of claims 88, 89 and 95 herein comprise a subtilase with a Y167W substitution of the patented claims. The rejection of record, as modified in view of the new claims filed 3 March 2006, is maintained because the record does not show that a requirement for restriction prevented Applicant from prosecuting the rejected claims in a common application or that administrative action by the USPTO is responsible for earlier issue of an application as a patent the claims of which are applied in the rejection of record.

2. Claims 88, 89, 91 and 95 are rejected for reasons of record under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 34, 56, 90, 111, and 121-123 of U.S. Patent No. 5,741,694. Although the conflicting claims are not identical, they are not patentably distinct from each other where modified subtilases and detergent compositions comprising same of claims 88, 89, 91 and 95 herein comprise a subtilase with a Y167W substitution of the patented claims. The rejection of record, as modified in view of the new claims filed 3 March 2006, is maintained because the record does not show that a requirement for restriction prevented Applicant from prosecuting the rejected claims in a common application or that administrative action by the USPTO is responsible for earlier issue of an application as a patent the claims of which are applied in the rejection of record.



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3. Claims 88, 91, 95, 96, 98, 101, 102 and 105 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,110,884 because Applicant's amendment adds both the Y167I and Y167L substitutions to the new claims 96 and 102 and adds both the Y171I and Y171L substitutions to the new claims 88, 91, and 98. Although the conflicting claims are not identical, they are not patentably distinct from each other because modified subtilisins, including subtilisins 309 and 147, and detergent compositions comprising same of the new claims 88, 91, 95, 96, 98, 101, 102 and 105 herein comprise Y167I and Y167L, and/or Y171I and Y171L substitutions, of the modified subtilisins, including subtilisins 309 and 147, and detergent compositions comprising same of the patented claims.

4. Claims 96, 99, 100, and 102-104 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3-6 of U.S. Patent No. 6,555,355 because Applicant's amendment adds the Y167I substitution in new claims 96 and 102. Although the conflicting claims are not identical, they are not patentably distinct from each other because the modified subtilases of the new claims 96, 99, 100, and 102-104 herein comprise the Y167I substitution of the patented claims 3-6 that may further comprise at least one ancillary modification or mutation at one or more of the positions 36, 57, 76, 97, 104, 120, 206, 218, 222, and 235.

5. Claims 96, 99, 100, and 102-104 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3-8 of U.S. Patent No. 6,558,938 because Applicant's amendment adds the Y167I substitution in new claims 96 and 102. Although the conflicting claims are not identical, they are not patentably distinct from each other because modified subtilases of the new claims 96, 99, 100, and 102-104 herein comprise the Y167I substitution of the patented claims 3-6

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that may further comprise at least one ancillary modification or mutation at one or more of the positions 36, 57, 76, 97, 104, 120, 206, 218, 222, and 235.

6. Claims 88-90, 92-94, 96, 99-100, and 102-104 are rejected, essentially for reasons of record, under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 17-19, 38-41, and 66-68 of U.S. Patent No. 6,605,458. Although the conflicting claims are not identical, they are not patentably distinct from each other because modified subtilases of claims 88-90, 92-94, 96, 99-100, and 102-104 herein comprise several amino acid substitutions at positions Y167, Y170 and 194, including the Y167I and Y167L substitutions added by Applicant's amendment in new claims 88, 96, and 102, embraced by the generic substitutions recited as "Y167", "Y170", and "194" in modified subtilases of the patented claims that further comprise at least one ancillary substitution or deletion at one or more of the positions 36, 57, 76, 97, 104, 120, 206, 218, 222, and 235. The rejection of record, as modified in view of the new claims filed 3 March 2006, is maintained because the record does not show that a requirement for restriction prevented Applicant from prosecuting the rejected claims in a common application or that administrative action by the USPTO is responsible for earlier issue of an application as a patent the claims of which are applied in the rejection of record.

7. Claims 88-90, 92-94, 96, 99-100, and 102-104 are rejected, essentially for reasons of record, under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 10-14, 35-39, 60-64, 86-90, 111-115, 136-140, 161-165, 186-190, and 211-215 of U.S. Patent No. 6,773,907. Although the conflicting claims are not identical, they are not patentably distinct from each other because modified subtilases of claims 88-90, 92-94, 96, 99-100, and 102-104 herein comprise several amino acid substitutions at positions Y167, Y170, and 194, including the Y167I and

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Y167L substitutions added by Applicant's amendment in new claims 88, 96, and 102, embraced by the generic substitutions recited as "Y167X", "Y170X", and "194" in modified subtilases of the patented claims that further comprise at least one ancillary substitution or deletion at one or more of the positions 36, 57, 76, 97, 104, 120, 194, 206, 218, 222, and 235. The rejection of record, as modified in view of the new claims filed 3 March 2006, is maintained because the record does not show that a requirement for restriction prevented Applicant from prosecuting the rejected claims in a common application or that administrative action by the USPTO is responsible for earlier issue of an application as a patent the claims of which are applied in the rejection of record.

8. Claims 88-90, 93-96, and 99-104 are rejected, essentially for reasons of record, under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 8, 9, 22, and 23 of U.S. Patent No. 6,777,218. Although the conflicting claims are not identical, they are not patentably distinct from each other because modified subtilases of claims 88-90, 93-96, and 99-104 herein comprise several amino acid substitutions at positions Y167 and Y170, including the Y167I and Y167L substitutions Applicant's amendment added to the new claims 88, 96, and 102, embraced by the generic substitutions recited as "Y167X" and "Y170X" in modified subtilases of the patented claims that further comprise at least one ancillary substitution or deletion at one or more of the positions 36, 57, 76, 97, 104, 120, 206, 218, 222, and 235. The rejection of record, as modified in view of the new claims filed 3 March 2006, is maintained because the record does not show that a requirement for restriction prevented Applicant from prosecuting the rejected claims in a common application or that administrative action by the USPTO is responsible for earlier issue of an application as a patent the claims of which are applied in the rejection of record.

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9. Claims 88-90, 92-94, 96, 99-100, and 102-104 are rejected, essentially for reasons of record, under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 9-13, 33-37, 57-61, 81-85, 105-109, 129-133, 153-157, and 177-181 of U.S. Patent No. 6,780,629. Although the conflicting claims are not identical, they are not patentably distinct from each other because modified subtilases of claims 88-90, 92-94, 96, 99-100, and 102-104 herein comprise several amino acid substitutions at positions Y167, Y170, and 194, including the Y167I and Y167L substitutions added by Applicant's amendment in new claims 88, 96, and 102, embraced by the generic substitutions recited as "Y167X", "Y170X", and "194" in modified subtilases of the patented claims that further comprise at least one ancillary substitution or deletion at one or more of the positions 36, 57, 76, 97, 104, 120, 194, 206, 218, 222, and 235. The rejection of record, as modified in view of the new claims filed 3 March 2006, is maintained because the record does not show that a requirement for restriction prevented Applicant from prosecuting the rejected claims in a common application or that administrative action by the USPTO is responsible for earlier issue of an application as a patent the claims of which are applied in the rejection of record.

10. Claims 88, 90, and 92-95 are rejected, essentially for reasons of record, under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 6 and 7 of U.S. Patent No. 6,808,913. Although the conflicting claims are not identical, they are not patentably distinct from each other because modified subtilases and detergent compositions comprising same of claims 88, 90, and 92-95 herein comprise several amino acid substitutions at position 170 and 194 embraced by the generic substitutions recited as "170" and "194" in the modified subtilisin 309 of the patented claims that further comprise at least one ancillary modification or mutation at one or more of the positions 222 and 235 and detergent compositions comprising same.

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The rejection of record, as modified in view of the new claims filed 3 March 2006, is maintained because the record does not show that a requirement for restriction prevented Applicant from prosecuting the rejected claims in a common application or that administrative action by the USPTO is responsible for earlier issue of an application as a patent the claims of which are applied in the rejection of record.

11. Claims 88-90, 92-94, 96, 99-100, and 102-104 are rejected, essentially for reasons of record, under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 16-22 of U.S. Patent No. 6,893,855. Although the conflicting claims are not identical, they are not patentably distinct from each other because modified subtilases of claims 88-90, 92-94, 96, 99-100, and 102-104 herein comprise several amino acid substitutions at positions Y167, Y170, and 194, including the Y167I and Y167L substitutions added by Applicant's amendment in new claims 88, 96, and 102, embraced by the generic substitutions recited as "167", "170", and "194" in modified subtilases of the patented claims that further comprise at least one ancillary substitution or deletion at one or more of the positions 36, 57, 76, 97, 104, 120, 194, 206, 218, 222, and 235. The rejection of record, as modified in view of the new claims filed 3 March 2006, is maintained because the record does not show that a requirement for restriction prevented Applicant from prosecuting the rejected claims in a common application or that administrative action by the USPTO is responsible for earlier issue of an application as a patent the claims of which are applied in the rejection of record.

12. Claims 88-90, 92-94, 96, 99-100, and 102-104 are rejected, essentially for reasons of record, under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 5, 8, 10-13, 18-21, and 23-28 of U.S. Patent No. 6,921,657. Although the conflicting claims are not identical, they are not patentably distinct from each other because modified subtilases of claims 88-90, 92-94, 96, 99-

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100, and 102-104 herein comprise several amino acid substitutions at positions Y167, Y170, and 194, including the Y167I and Y167L substitutions added by Applicant's amendment in new claims 88, 96, and 102, embraced by the generic substitutions recited as "167", "170", and "194" in modified subtilases of the patented claims that further comprise at least one ancillary substitution or deletion at one or more of the positions 36, 57, 76, 97, 104, 120, 194, 206, 218, 222, and 235. The rejection of record, as modified in view of the new claims filed 3 March 2006, is maintained because the record does not show that a requirement for restriction prevented Applicant from prosecuting the rejected claims in a common application or that administrative action by the USPTO is responsible for earlier issue of an application as a patent the claims of which are applied in the rejection of record.

13. Claims 88-90, 92-94, 96, 99-100, and 102-104 are rejected, essentially for reasons of record, under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 10-14 of U.S. Patent No. 7,026,153. This rejection was formerly a provisional double-patenting rejection based on claims of application serial No. 10/403,105 but the application claims are now patented claims. Although the conflicting claims are not identical, they are not patentably distinct from each other because modified subtilases of claims 88-90, 92-94, 96, 99-100, and 102-104 herein comprise amino acid substitutions at positions Y167, Y170, and 194, including the Y167I and Y167L substitutions added by Applicant's amendment in new claims 88, 96, and 102, embraced by the generic substitutions recited as "167", "170", and "194" in modified subtilases of the patented claims that further comprise at least one ancillary substitution or deletion at one or more of the positions 36, 57, 76, 97, 104, 120, 194, 206, 218, 222, and 235. The rejection of record, as modified in view of the new claims filed 3 March 2006, is maintained because the record does not show that a requirement



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for restriction prevented Applicant from prosecuting the rejected claims in a common application or that administrative action by the USPTO is responsible for earlier issue of an application as a patent the claims of which are applied in the rejection of record.

*B. Provisional Double Patenting*

The following, several, rejections are provisional obviousness-type double patenting rejections because the conflicting claims have not in fact been patented.

1. Claims 88-90 and 92-95 are provisionally rejected, essentially for reasons of record, under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 74, 77, and 78 of copending application serial No. 09/931,701. Although the conflicting claims are not identical, they are not patentably distinct from each other because recited substitutions at positions 167, 170 and 194 of the modified subtilases of claims 88-90 and 92-95 herein are embraced by the generic substitutions at positions 167, 170, and 194 of modified subtilases of the copending application's claims that further comprise at least one ancillary substitution or deletion at one or more of the positions 36, 57, 76, 97, 104, 120, 206, 218, 222, 235, and 274 and detergent compositions comprising same. The rejection of record, as modified in view of the new claims filed 3 March 2006, is maintained because the record does not show that a requirement for restriction prevented Applicant from prosecuting the rejected claims in a common application or that administrative action by the USPTO is responsible for earlier issue of an application as a patent the claims of which are applied in the rejection of record.

2. Claims 88-91, 93, and 94 are provisionally rejected, essentially for reasons of record, under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 101, 102, and 105-111 of copending application serial No. 09/948,080. Although the conflicting claims are not identical, they are not

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patentably distinct from each other because modified subtilases of claims 88-91, 93, and 94 herein comprise substitutions at positions 167, 170, and 171 that are also substitutions indicated for the modified subtilases of the copending application's claims that further comprise at least one ancillary substitution or deletion at one or more of the positions 36, 57, 76, 97, 104, 120, 206, 218, 222, and 235 and detergent compositions comprising same. The rejection of record, as modified in view of the new claims filed 3 March 2006, is maintained because the record does not show that a requirement for restriction prevented Applicant from prosecuting the rejected claims in a common application or that administrative action by the USPTO is responsible for earlier issue of an application as a patent the claims of which are applied in the rejection of record.

4. Claims 88, 89, and 91-109 are provisionally rejected, essentially for reasons of record, under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 8, 19, 28, 41, 44, 45, 55, and 74 of copending application serial No. 10/314,191. Although the conflicting claims are not identical, they are not patentably distinct from each other because substitutions indicated for positions 136, 167, 171, and 194 of modified subtilases of claims 88, 89, and 91-109 herein, and detergent compositions comprising same, are embraced by the generic substitutions at positions 136, 167, 171, and 194 of modified subtilisins 309, 147, and PB92, of the copending application's claims that further comprise at least one ancillary substitution or deletion at one or more of the positions 27, 76, 101, and 206, and detergent compositions comprising same. The rejection of record, as modified in view of the new claims filed 3 March 2006, is maintained because the record does not show that a requirement for restriction prevented Applicant from prosecuting the rejected claims in a common application or that administrative action by the USPTO is responsible for

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earlier issue of an application as a patent the claims of which are applied in the rejection of record.

5. Claims 88, 90, and 93-95 are provisionally rejected, essentially for reasons of record, under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 16 and 49-54 of copending application serial No. 10/699,394. Although the conflicting claims are not identical, they are not patentably distinct from each other because modified subilases of claims 88, 90, and 93-95 herein, and detergent compositions comprising same, comprise one or more of the generic substitutions at position 170 recited in the preamble of claim 16 of the copending application that further comprises at least one ancillary substitution or deletion at one or more of the positions 27, 57, 76, 120, 206, 218, and 222 and detergent compositions comprising same. The rejection of record, as modified in view of the new claims filed 3 March 2006, is maintained because the record does not show that a requirement for restriction prevented Applicant from prosecuting the rejected claims in a common application or that administrative action by the USPTO is responsible for earlier issue of an application as a patent the claims of which are applied in the rejection of record.

6. Claims 88-90, 92, 93, 96, 97, 99, 102, and 103 are provisionally rejected, essentially for reasons of record, under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 90-96 and 129-135 of the copending application serial No. 10/884,325. Although the conflicting claims are not identical, they are not patentably distinct from each other because modified subilases of claims 88-90, 92, 93, 96, 97, 99, 102, and 103 herein comprise one or more of the generic substitutions at positions 167, 170, and 194 of modified subilases of the copending application's claims that further comprise at least one ancillary substitution or deletion at one or more of the positions 27, 36, 76, 97, 101, 104, 120, 123, 206, 218, 222, and 235.

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The rejection of record, as modified in view of the new claims filed 3 March 2006, is maintained because the record does not show that a requirement for restriction prevented Applicant from prosecuting the rejected claims in a common application or that administrative action by the USPTO is responsible for earlier issue of an application as a patent the claims of which are applied in the rejection of record.

7. Claims 88, 90, and 93-95 are provisionally rejected, essentially for reasons of record, under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 25, 28, 29, and 32-34 of copending application serial No. 10/896,177. Although the conflicting claims are not identical, they are not patentably distinct from each other because modified subtitlases of claims 88, 90, and 93-95 herein are embraced by the generic substitutions at position 170 of a modified subtilisin 309 of the copending application that further comprise at least one ancillary substitution at one or more of the positions 218 and 222 and detergent compositions comprising same. The rejection of record, as modified in view of the new claims filed 3 March 2006, is maintained because the record does not show that a requirement for restriction prevented Applicant from prosecuting the rejected claims in a common application or that administrative action by the USPTO is responsible for earlier issue of an application as a patent the claims of which are applied in the rejection of record.

*Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 88, 91, 95, 96, 101, 102, and 105 are rejected under 35 U.S.C. § 102(e) as being anticipated by Rasmussen et al., US 6,110,884, of record.

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This new ground of rejection is necessitated by Applicant's inclusion of the Y167I and Y167L substitutions in clauses (b) of the new claims 96 and 102 as well as Applicant's inclusion of the Y171I and Y171L substitutions in clause (c) of the new claim 88. Rasmussen et al. disclose subtilisin 309 and 147 variants comprising any of Y167I, Y167L, Y171I, and Y171L substitutions as well as detergent compositions comprising same. See claims 1-3 and 8, anticipating the claimed subject matter.

*Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 93, 94, 99, 100, 103, and 104 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Rasmussen et al., US 6,110,884, in view of Branner et al., US 5,482,849, both discussed above.

This new ground of rejection is necessitated by Applicant's presentation of the new claims 96 and 98-109. The teachings of Rasmussen et al., discussed above, are taken as before. Branner et al. teach the preparation of subtilase variants having multiple amino acid substitutions, including substitutions at the subtilisin BPN'-correspondent positions 167 and 171, that may be further combined with other substitutions at, e.g., subtilisin BPN'-correspondent positions 27, 120, and 235, and the incorporation of such multiply-substituted subtilase variants into detergent compositions. See e.g., claims 1, 8, 9, 21, 30-39 and 42-45. It would have been obvious to one of ordinary skill in the art at the time the invention was made to make any of the Y167I, Y167L, Y171I, and Y171L substitutions of Rasmussen et al. in any of the many subtilisins, including the subtilisins 309, 147, and PB92 taught by Branner et al. in addition to the other substitutions made at these positions by Branner et al., and also to further combine any of the Y167I,



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Y167L, Y171I, and Y171L substitutions at the further substitutions taught and claimed by Branner et al, because such an artisan would have had a reasonable expectation that subtilase variants comprising such Y167I, Y167L, Y171I, and Y171L substitutions would have advantageous properties as suggested by Rasmussen et al., as much they would have the advantageous properties as suggested by Branner et al. for different substituents at the same two positions. Such an artisan would have been motivated to do so in view of the increasingly crowded art of subtilisin modification at that time.

Claims 96 and 98-109 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Bott et al., US 5,700,676, of record, in view of Branner et al., US 5,482,849, of record.

This new ground of rejection is necessitated by Applicant's presentation of the new claims 96 and 98-109. Bott et al. teach in Table II that the tyrosine at position 171 in the amino acid sequence of the mature subtilisin BPN' may advantageously be substituted by glutamine, among other amino acids. Branner et al. teach the preparation of subtilase variants having multiple amino acid substitutions, including substitutions at the subtilisin BPN'-correspondent position 171, and the incorporation of such variants into detergent compositions, wherein the subtilase variant may be a "subtilisin 309, subtilisin 147, [and] Bacillus PB92 protease". See e.g., claims 1, 8, 9, 21, 30-39 and 42-45. It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the Y171IQ substitution of Bott et al. in any of the many subtilisins, including the subtilisins 309, 147, and PB92 taught by Branner et al. in addition to the other substitutions made at this position by Branner et al., and also to further combine the Y171IQ substitution of Bott et al. at the further substitutions taught and claimed by Branner et al, because such an artisan would have had a reasonable expectation that subtilase variants comprising such a Y167Q substitution would have advantageous properties as suggested by Bott et al., as much they would have the advantageous



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properties as suggested by Branner et al. for different substituents at the same position. Such an artisan would have been motivated to do so in view of the increasingly crowded art of subtilisin modification at that time.

### *Conclusion*

While subject to several rejections above under the judicially created doctrine of obviousness-type double patenting, claims 97 and 110-116 are free of the prior art of record herein where the E134K substitution made in subtilisins 309 and PB92 – at the position corresponding to 136 in subtilisin BPN' – by Mulleners et al., US 5,324,653, of record, does not meet the limitations of the claims and the subsequently disclosed E134C substitution made in subtilisins 309 and PB92 – at the position corresponding to 136 in subtilisin BPN' – by Mulleners et al., US 6,287,841, of record, is not prior art to an invention claimed herein. Similarly, the E136Q substitutions disclosed by Casteleijn et al., EP 0405901, Branner et al., WO 91/00345 and WO 92/11357, and Åaslyng et al., U.S. Patents Nos. 5,665,587 and 6,197,567, all of record, do not meet the limitations of claims 97 and 110-116. Deletion of recitations in the pending claims of positions 167, 170, 171 and 194 and their substituents together with provision of an appropriate terminal disclaimer over those patents whose claims implicate position 136 and the eight substituents recited by claims 97 and 110-116 would permit the allowance of the remaining claims.

### *Conclusion*

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

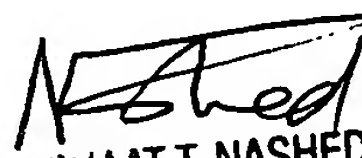
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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William W. Moore whose telephone number is 571.272.0933 and whose FAX number is 571.273.0933. The examiner can normally be reached Monday through Friday between 9:00AM and 5:30PM EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisory Primary Examiner, Dr. Kathleen Kerr, can be reached at 571.272.0931. The official FAX number for all communications for the organization where this application or proceeding is assigned is 571.273.8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571.272.1600.

William W. Moore  
8 June 2006

  
NASHAAT T. NASHED PHD.  
PRIMARY EXAMINER